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Our case docket no: 461

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Washington, D.C. 20231

Sir: Transmitted herewith for filing is the patent application of inventor(s):

W. GARDNER RHEA, JR. MD.

For: MULTIFUNCTION CATHETER

Enclosed also are:

Combined Oath, Declaration, Petition, and Pwr. of Atty.;

One sheet of drawings;

Small Entity Declaration;

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Claims as filed				
For	Number filed	Number extra	Rate	Basic Fee plus
Total Claims	8 - 20	0	xxxxxxx	00
Independent Claims	2 - 3	0	xxxxxx	00
Basic Fee	\$395.00	Total Filing Fee		\$395.00

Respectfully submitted,



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Agent of record; my agents license no. is 27-486

USPS U.S. PTO
10/27/97

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262201-60385680

Applicant or Patentee: W. GARDNER RHEA, JR., MD Atty. Docket No. 461

Serial or Patent No.: _____

~~Filed or Issued~~ xxx Executed: 10/19/97

For: MULTIFUNCTION CATHETER

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY
STATUS UNDER 37 CFR 1.9, 1.27, AND 1.28

I hereby declare that each individual, concern or organization having rights to the invention is listed below and no rights to the invention are held by any person, other than the inventor, who would not qualify as a small business concern under 37 CFR 1.9(d) or any concern which would not qualify as a small business concern under 37 CFR 1.9(d).

NAME: _____ NONE _____

ADDRESS: _____

☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN

NAME: _____

ADDRESS: _____

☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b)).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which the verified statement is directed.

NAME OF PERSON SIGNING W. GARDNER RHEA, JR., MD

TITLE IN ORGANIZATION Individual-Inventor

ADDRESS OF PERSON SIGNING 101 BORING CIRCLE

LAFAYETTE, LOUISIANA 70506

signature



DATE 10/19/97

NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities (37 CFR 1.27)

00958509-102797

IN THE UNITED STATES PATENT
AND
TRADEMARK OFFICE

* * * * *

APPLICATION OF

W. GARDNER RHEA, JR.

FOR

UNITED STATES LETTERS PATENT

ON

MULTIFUNCTION CATHETER

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MULTIFUNCTION CATHETER

This invention pertains to a medical catheter for insertion into the human body. More particularly, the catheter is adapted for, but not limited to, insertion along the urethra into the bladder to measure various vital signs as well as to drain the bladder.

BACKGROUND OF THE INVENTION

In trauma and many operative cases it is customary to insert a catheter into the bladder very early on to drain the bladder, detect some forms of internal damage, and monitor urinary output, and potentially provides passage for insertion of other instruments. Temperature measurements can be readily made by way of the catheter duct with electronic sensors now available. Internal pressure, intra-abdominal, may need to be monitored in many cases and here also electronic related sensors provide means to monitor pressure by way of the catheter access. The mucosa lining the genito-urinary and gastro-intestinal tracts has vascular features that facilitate blood oxygen level determinations. The usual practice involves the use of a light source and a light sensitive sensor, attached to available body areas, that indicates oxygen level in the blood by it's light response characteristics. Externally applied, these systems sometimes become dislodged. Modern light sources and sensors suggest the use of the catheter structure as convenient access for oximeter functions. The vessels of the mucosa pulse with the heartbeat and provide a convenient pulse rate detector with readily available adaptation of the electronic signal processor activity related to the blood oxygen sensor.

The development of miniature sensors and closely related signal carriers invited and was attended by an increase in the number of data gathering functions considered necessary. The apparatus grew smaller but the number increased. The work area became cluttered. Connections of monitoring devices to external instrumentation became more tedious and invited errors. The loss of monitor information at critical points was, and is, dangerous.

There is a need to combine a number of medical data gathering intrusive devices into the envelope of one of those devices deemed necessary so that the effect of only one intrusion is borne by the patient and patient care area. Further, when time is assumed to be vital, the use of a single catheter, capable of a plurality of functions, is of value in terms of time economy and certainty of correct connections. In addition, the security of device placement and the acquisition of reliable data, being critical, is significantly advanced by the combination of these modalities.

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2 It is therefore an object of this invention to provide via the catheter apparatus a
3 combination of data gathering functions in one catheter envelope.

4 It is yet another object of this invention to provide a urethral catheter with a built in
5 temperature measuring capability, a built in pressure measuring capability, a built in blood
6 oxygen measuring capability and a built in pulse rate measuring ability, with a balloon near
7 the insertion end of the catheter for anchoring the assembly within the urinary bladder, thus
8 assuring the correct and stable placement of the various monitoring devices.

9 These and other objects, advantages, and features of this invention will be apparent to
10 those skilled in the art from a consideration of this specification, including the attached claims
11 and appended drawings.

12 13 SUMMARY OF THE INVENTION

14 A modified Foley catheter has fluid conduits molded into the tube wall material to
15 provide a passage to inflate a balloon near the insertion end for anchoring the catheter in the
16 body. Wire conductors, and fiber optics elements if used, imbedded in the catheter structure
17 provide power and sensor related circuits for a light near the insertion end, a temperature
18 sensor, a pressure sensor and a blood oxygen level sensor. The associated external
19 instrumentation, not part of this disclosure, provides power control and interpreter functions
20 for the light, the pressure sensor, and the temperature sensor. The oxygen sensor reacts to the
21 light characteristics as modified by vascular content between the light source and the sensor
22 and, in conjunction with associated external signal processing means, alluded to above,
23 processes the signal to provide an indication of the level of oxygen in the blood. The
24 instrumentation related to the oxygen sensing action can, within the realm of current art,
25 responds to the pulsation of light received by that sensor and provide signal conditioning
26 ability to indicate pulse rate. No additional conductors and sensors are needed for the pulse
27 sensing function. The light source and oximeter sensor emit and receive through a thin
28 portion of the catheter wall. The catheter, in general, follows the well known Foley
29 configuration.

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3 BRIEF DESCRIPTION OF DRAWINGS

4 In the drawings wherein like features have similar captions, figure 1 is a side view of
5 the novel catheter.

6 Figure 2 is a fragmentary side view, somewhat enlarged, and partially cut away, of the
7 insertion end of the novel catheter.

8 Figure 3 is a side view, similar in scale of that of figure 2 but showing an area farther
9 yet from the insertion end.

10 Figure 4 is a side view, similar in scale to that of figure 2 but showing a region farther
11 from the insertion end in the region captioned as 3 in figure 1.

12 Figure 5 is an orthogonal view of the view of figure 4.

13 DETAILED DESCRIPTION OF DRAWINGS

14 In the drawings certain features well established in the art and not bearing upon points
15 of novelty are omitted in the interest of descriptive clarity. Such omitted features may include
16 layered structure of the general embodiment.

17 In figure 1, tubular body 1 is terminated by funnel opening end 4b at the access end
18 and tapered insertion end 2. The usual generally central catheter conduit 4 extends from the
19 common opening 4b at the access end to the dual openings 4a near the tip of the insertion
20 end. The retention balloon 5 is shown inflated by dashed lines. Intrinsic light sources and
21 sensors distributed along length 3, yet to be described, depend upon the usual external
22 control and signal processing means to be connected by the multi-conductor connector 8
23 pending from neck 7. Preferably, all imbedded conductors terminate in one connector.
24 External circuitry demands may dictate separate connectors for different groups of
25 conductors in which case more than one connector, pending from related necks, will be used.
26 The balloon requires a fluid conduit, described later, and that conduit terminates in opening
27 5b in nipple 10 pending from neck 9.

28 In figure 2, the insertion end is enlarged and passage end 4 is shown to open from the
29 sides 4a of the point 2. Element 13 is a pressure sensor of a miniature type that is commonly
30 available and is imbedded, or molded, into the wall of the end portion of the catheter. Wires
31 14, probably two, are imbedded in the catheter general structure.

32 Figure 3 relates to a balloon arrangement that is used to anchor the catheter within
33 the body. Annular plenum, or peripheral chamber, 5a, with a thin membrane outer shroud 5c,
34 is intrinsic to the catheter tube, sometimes attached as a membrane sleeve, surrounds the
35 catheter body and is fluidly connected with channel 5b by which the annular space can be

1 expanded by inflation to provide a bulge 5 on the catheter to anchor it in the body. This
2 balloon structure is common to the well known Foley catheter. Dashed lines illustrate the
3 expansion nature of the balloon feature.

4 Figure 4 shows the light emitting device, fiber optic or diode, 3a molded into the
5 catheter wall and arranged to emit light outward through a covering compatible with the
6 catheter purpose. The light sensitive sensor 3b, also molded into the catheter wall, is arranged
7 to receive light, fluorescently responsive to or reflected from the surrounding tissue in
8 response to light projected from source 3a. The sensor is selected and arranged to produce an
9 electrical output characteristic that is related to the blood oxygen concentration in the
10 illuminated tissue. The sensor is dependent upon external signal processor means to be
11 accessed by conductors imbedded, or molded into, the catheter wall and those conductors are
12 captioned as a group 3e emerging from the cutaway catheter. Conductors shown are
13 symbolic and may involve several individual conductors as required by the particular
14 contrivances specified. When associated with external signal processor means, the sensor, as
15 a pulse and oximeter component, is old art and currently available.

16 Figure 5 is an orthogonal projection of figure 4. Temperature sensor 3c, not visible in
17 figure 4, is imbedded in the catheter wall and has an associated conductor means 3d, also
18 embedded. Arrows P and R represent light paths permitted by the catheter outer material.
19 The conductor means may include a ground line common to all electrical contrivances in the
20 catheter, all of which will eventually lead to the connector 8. The temperature sensor is old
21 art, when associated with external signal processor means.

22 Well established in the instrumentation art the light source and sensors defined herein
23 and accessible by way of connector 8 will be supplied with a specification known as "pin
24 outs" that relate the characteristics of the imbedded electrical contrivances. From the "pin
25 out" specifications, instrument specialists define the related external signal conditioner and
26 indicator, including recorder, systems that empower the catheter user to utilize the catheter
27 system for the intended purpose. Every sensor intrinsic to the novel catheter is now in use in
28 the medical community in one form or another and the total functions defined herein can be
29 achieved by a plurality of available devices. In the realm of patient management related
30 activities, the plurality is a problem in that an assembly of individual systems take time, space,
31 attention to detail, and generally clutter up a busy environment where time saved, certainty of
32 function, and simplicity of installation can save lives.

33 It will be understood that certain features and sub-combinations are of utility and may
34 be employed without reference to other features and sub-combinations. This is contemplated
35 by and is within the scope of the claims.

1 As many possible embodiments may be made of the catheter of this invention without
2 departing from the scope thereof, it is to be understood that all matter herein set forth or
3 shown in the accompanying drawings is to be interpreted as illustrative and not in a limiting
4 sense.

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The invention having been described, I claim,

1 1. A catheter device arranged to empower a plurality of functions with a single
2 insertion operation, the catheter comprising:

3 a) a urethral-type catheter having an insertion end and an access end and a connecting
4 tube;

5 b) a pressure sensor imbedded into said insertion end;

6 c) a temperature sensor imbedded into the wall of said tube, near said insertion end
7 and arranged to produce an electric signal with characteristics determined by temperature
8 sensed;

9 d) a light emitter means imbedded into said wall arranged to project light outward
10 from the outside surface of said tube in response to electric energy provided thereto;

11 e) a color discriminating light sensitive detector means molded into the wall of said
12 tube and arranged to produce an electric signal with characteristics determined by the
13 characteristics of light energy received from the urethral lining outside said catheter;

14 f) an inflatable balloon intrinsic to said catheter tube wall, near said insertion end,
15 comprising a peripheral chamber in said tube wall;

16 g) a plurality of conductors imbedded in said catheter wall, at least one connected to
17 each said emitter, said light detector, said temperature sensor and said pressure sensor, each
18 terminating in an at least one conductor connector near said access end; and

19 h) a fluid conductor tube imbedded in said catheter wall, fluidly connected to said
20 peripheral chamber and opening as a tubular connector extending from said catheter near said
21 access end;

22 whereby said light detector, when in use adjacent mucosa receives light energy
23 produced by said light source as conditioned by said mucosa and whereby said catheter
24 provides a terminal end for associated external signal conditioner, control and indicator
25 output means.

1 2. The catheter of claim 1 wherein said connector is connected to said catheter by a
2 flexible extension.

1 3. The catheter of claim 1 wherein said pressure sensor is imbedded near the catheter
2 outer wall in said insertion end.

1 4. The catheter of claim 1 wherein said balloon is situated along said catheter tube
2 between said insertion end and said temperature sensor.

1 5. The catheter of claim 1 wherein said balloon is situated along said catheter tube
2 between said insertion end and said light emitting and light sensitive detector means.

1 6. The catheter of claim 1 wherein said light emitting means and said light detector
2 are covered by a thin membrane that provides the outer surface of said catheter.

1 7. The catheter of claim 1 wherein said peripheral chamber is provided by a tubular
2 membrane secured to the external surface of said catheter.

1 8. *A modified Foley catheter comprising intrinsic pressure sensor means, temperature*
2 *sensor means, and oximeter means imbedded in the material forming the wall of the tubular*
3 *extension and provided with at least one electrical connector at the access end, said*
4 *connector providing access to conductors imbedded in the tube wall to transmit excitation*
5 *energy and signal communication between said connector and external control and signal*
6 *conditioning means to provide readout information defining temperature, pressure, blood*
7 *oxygen levels and pulse rate for a patient fitted with the catheter.*

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5 ABSTRACT OF THE DISCLOSURE
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7 A modified Foley type catheter has a pressure sensor near the insertion end, an
8 inflatable balloon, a temperature sensor, a light emitting means, and a blood oxygen level
9 detector near the light emitting means, all molded into the catheter tube wall. The oxygen
10 level sensor is arranged to receive light energy from tissue illuminated by the light source. All
11 required electrical conductors, and fiber optics elements if used, are molded into the catheter
12 wall and terminate in a connector near the access end. The balloon has a fluid supply conduit,
13 or channel, molded into the catheter wall and it terminates in a connector nipple near the
14 access end. A pulse detector means is derived from the association of the oxygen level sensor
15 and the required external signal processing means. All associated external signal processing
16 means and output indicator means currently exists for observation and recording. Rewiring
17 for suitable connector association with the novel catheter is well established in the art.

FIG. 1

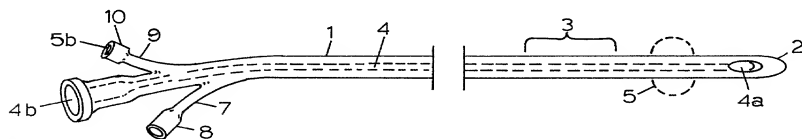


FIG. 3

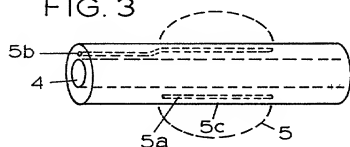


FIG. 2

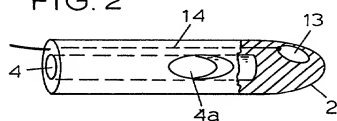


FIG. 4

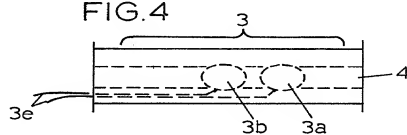
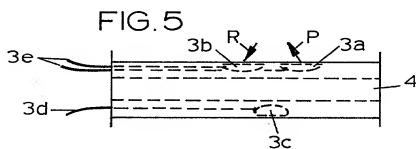


FIG. 5



OATH, DECLARATION, PETITION, AND POWER OF ATTORNEY

I, as the below named inventor, declare that:

My residence, Post Office address, and citizenship is as stated below, next to my name.

I believe I am the original, first, and sole inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled

MULTIFUNCTION CATHETER

the specification of which is attached hereto;

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendments referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56.

I have not, through my own actions or actions of any of my representatives, filed any foreign applications for patents or inventors certificates for the above identified invention before the date of this declaration.

As the named inventor, I hereby appoint John D. Jeter, registration number 27,486, address, 1403 Teche drive, St. Martinville, Louisiana, 70582, whose telephone number is (318)394-5017, my agent to prosecute this application and to transact all business in the Patent Office connected therewith.

Wherefore, I pray that a Letters Patent be granted to me for the invention or discovery described and claimed in the foregoing specification and claims, and I hereby subscribe my name to the foregoing specification and claims, declaration, power of attorney, and this petition.

I declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of inventor: W. GARDNER RHEA, JR., MD date 10/19/97

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